Guidance for Industry

Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's or Agency's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended for outsourcing facilities that compound human drugs (outsourcing facilities). A facility that compounds sterile drugs may elect to register with FDA as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b), as added by the Drug Quality and Security Act (DQSA). This guidance focuses on electronic submission of establishment registration information.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Drug Quality and Security Act

The DQSA adds new section 503B to the FD&C Act. Under section 503B(b) of the FD&C Act, a compounder may elect to become an outsourcing facility by registering with FDA. Each registered outsourcing facility must report to the Agency certain information about the products it compounds. Products compounded in a registered outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act (21 U.S.C. 355) and the requirement to label products with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) if the requirements in section 503B are met.

[1] This guidance was prepared by the Office of Compliance, Center for Drug Evaluation and Research, at the Food and Drug Administration.

Outsourcing facilities will be inspected by FDA and must comply with other provisions of the FD&C Act, such as current good manufacturing practice (cGMP) requirements. Information about these requirements will be provided separately at a later date.

After the initial registration, under section 503B(b) of the FD&C Act, a facility that elects to register with FDA as an outsourcing facility must also do so annually between October 1 and December 31. Upon registration, the outsourcing facility must provide its name, place of business, a unique facility identifier, and a point of contact email address. The outsourcing facility must also indicate whether it intends to compound, within the next calendar year, a drug that appears on FDA's drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e), and whether it compounds from bulk drug substances, and, if so, whether it compounds sterile drugs.

B. Scope of This Guidance

This guidance document describes the process for registering as an outsourcing facility under section 503B of the FD&C Act. A separate guidance provides instruction on how outsourcing facilities should report to FDA the products they compound.[2] This guidance reflects current thinking in light of data standards, information technology, and information management resources. As these variables change over time, FDA may revisit this guidance and the specifications described in section III of this guidance.

III. REGISTERING WITH FDA AS AN OUTSOURCING FACILITY

A. Who Should Register

A facility that compounds sterile drugs may elect to register with FDA as an outsourcing facility. Each facility at a separate geographic location or address must register separately. The outsourcing facility is not required to be a licensed pharmacy, and may or may not obtain prescriptions for individual patients.

B. How to Register

1. Primary Method for Outsourcing Facility Registration

Facilities that elect to register with FDA as outsourcing facilities should submit registration information using the existing Structured Product Labeling (SPL) format. For detailed instructions on how to submit information using SPL, outsourcing facilities should refer to

[2] See the draft guidance for industry *Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*. When final, this guidance will represent FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

section IV of the guidance for industry *Providing Regulatory Submissions in Electronic Format — Drug Establishment Registration and Drug Listing*.[3]

After initial registration, facilities must register annually, between October 1 and December 31 of each year, to be registered outsourcing facilities. FDA has created a new SPL category of business operation for outsourcing facilities. All outsourcing facilities should submit establishment registration information using the business operation "Human Drug Compounding Outsourcing Facility." If a facility chooses to register as an outsourcing facility, it is required by section 503B(b) of the FD&C Act, and as described above, to submit the following information:

- Name of the facility;
- Place of business;
- Unique facility identifier;
- Point of contact email address;
- An indication of whether the facility intends to compound products on FDA's drug shortage list; and
- An indication of whether the facility compounds from bulk drug substances, and if so, whether it compounds sterile drugs from bulk drug substances.[4]

FDA also encourages outsourcing facilities to include a phone number as part of their registration information.

2. Alternative Interim Registration Method

FDA encourages outsourcing facilities to register using FDA's electronic registration system, as described in III.B.1 above. However, because registration is a new requirement for those outsourcing facilities that elect to register under section 503B, and because FDA wants to encourage registration of outsourcing facilities, FDA is providing an alternative interim registration mechanism for use after initial passage of the DQSA.

If an outsourcing facility new to FDA's electronic registration method chooses to register by this alternative interim method, the following information should be submitted in an email to edrls@fda.hhs.gov:

- Name of the facility;
- Place of business;
- Unique facility identifier;
- Point of contact email address;

[3] Available on the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[4] Although section 503B(b)(1)(A) does not specifically identify this information, section 503B(b)(1)(B)(ii) requires FDA to publish this information on the Internet (see section III.B.3 below). Therefore, FDA is requiring that this information be supplied as part of the registration submission.

- An indication of whether the facility intends to compound products on FDA's drug shortage list; and
- An indication of whether the facility compounds from bulk drug substances, and if so, whether it compounds sterile drugs from bulk drug substances.

FDA also encourages outsourcing facilities to include a phone number as part of their registration information.

This alternative interim registration method is only intended for use in the near term, while outsourcing facilities unfamiliar with registration familiarize themselves with the method described in section III.B.1. FDA encourages outsourcing facilities that choose to use this alternative interim method to begin using the method described in section III.B.1 no later than September 30, 2014.

3. Posting of Registration Information

The information collected from the outsourcing facility registration, as well as certain product information, will be published in a list on the Internet as required by section 503B(b)(1)(B)(ii) of the FD&C Act. This list will include the name of each registered outsourcing facility, the state in which it is located, whether the facility compounds from bulk drug substances, and whether any bulk drug substance compounding is for sterile or nonsterile drugs.

C. Electronic Registration

Section 503B(b)(3) of the FD&C Act requires outsourcing facilities to register by electronic means unless FDA grants a request for a waiver of this requirement "because use of electronic means is not reasonable for the person requesting the waiver." FDA does not anticipate many instances in which electronic submission of registration information will not be reasonable for the person requesting the waiver. However, if you are granted a waiver, you will be instructed on how to submit the required registration information.

To apply for a waiver from the requirement to electronically submit drug establishment registration information, you should provide to the following address a written request with a complete explanation of why the use of electronic means is not reasonable for you:

Drug Registration and Listing System Team
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

or

Email: edrls@fda.hhs.gov

D. Registration Fees

Under the DQSA, an outsourcing facility is not considered registered until all registration fees owed by the facility have been paid (see section 503B(g)(3)(A) of the FD&C Act). However, an outsourcing facility can register without paying a fee until October 1, 2014, because under the DQSA fees will not be assessed or owed until after that date.